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**Performance Standards for
Geologic Disposal:
A Regulator's Perspective**

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**Performance Standards for Geologic Disposal: A
Regulator's Perspective**

- Process for establishing regulations
 - Background and goals
 - The steps in the process
- Major elements in performance standards
- A case study: EPA's standards for geologic disposal of radioactive waste (40 CFR 191)

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Regulatory Process: Background

- The development of U.S. standards is defined by
 - Legislative requirements
 - Policies of the regulatory agency
- Goals
 - Public information and involvement
 - Openness, no undue influence
 - Clear explanation and basis for regulations
- Failure to follow the process can lead to
 - Loss of public confidence
 - Implementation problems
 - Legal vulnerability
- No standard time frame for rule development

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Regulatory Process: How It Works

- Information gathering
- Proposed rule
- Public input, refine approach
- Final rule
- At each stage, there are different goals and requirements.

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Regulatory Process - Step 1: Information Gathering

- Serves as basis to develop technical criteria and regulatory approach
- Flexibility in methods is allowed and helpful
- Possible sources of information include
 - Internal research
 - Consultation with stakeholders
 - International cooperation and consultation
 - Independent reviews (U.S. National Academy of Sciences)
 - Announcement of intent to develop rule (optional)

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Regulatory Process - Step 2: Proposed Rule

- "Proposed rule" explains reasoning
- Written notice required, other informal mechanisms available (mailing lists, etc.)
- Must explain reasoning
 - Technical and policy considerations
 - Multiple options may be discussed
 - Supporting documents are made available
 - Specific issues may be highlighted for input

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Regulatory Process - Step 3: Public Input

- Equal information, access is crucial
 - Public hearings and meetings may be targeted (but not restricted) to certain stakeholders
 - Written comments can be submitted
 - Interaction with stakeholders in private is limited
- Internal consideration of input is crucial in developing, defending final rule
- Additional information gathering may occur (further internal research, consultation)

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Regulatory Process - Step 4: Final Rule

- Written notice required (other methods optional)
- Must provide final standards and explanation
 - Discussion of major comments, how considered
 - Rationale for final standards
 - Must be "logical outgrowth" of proposal, no completely new issues
 - Effective date and other legal aspects
 - Guidance, expectations for implementation can be provided
- Administrative reviews are also required to ensure consistency within and across Agencies

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Major Elements in Safety Standards for Geologic Disposal

- Baseline Conditions: source term, site conditions
- Time frame of analysis
- Events/scenarios to be considered
 - Exposure pathways of interest
 - Exclusion of "unlikely" events, combination of events
 - Human intrusion
- Receptor location and characteristics
 - Receptor location or "compliance boundary"
 - Individual or group receptors
 - Assumptions on ultimate land use and accessibility
 - Activity, rates of consumption
 - Non-human or environmental receptors

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Elements in Safety Standards for Geologic Disposal (page 9)

- Treatment of parameter uncertainty
 - Average
 - Worst case
 - Probabilistic analysis
- Form of results: risk, dose, concentration
- Required level of confidence
- Other
 - Quality assurance on data
 - Peer review
 - Model validation
 - Qualitative measures, sub-system performance
- Multiple compliance measures may apply with different time frames, scenarios, etc.

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Challenges for Regulating Geologic Disposal

- Source term may be uncertain or non-homogeneous
 - Radioactive decay
- Very long time frames -- significant implications for defining receptors and bounding uncertainty
 - Uncertainty in land use, institutional controls
 - Human intrusion scenarios
 - Evolution of natural processes
 - Definition of unlikely events
 - Demographic or behavioral patterns
- Challenges to verifying results
- Much different approach than regulation of other hazardous materials

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Case Study: EPA's Generic Standards for High-Level and Transuranic Waste (40 CFR 191)

- Apply to all disposal systems for high-level and transuranic waste
 - Applies to WIPP (with EPA as implementing agency)
 - Yucca Mountain exempt (site-specific standards)
- Limit individual annual doses from operations
- For disposal phase, three primary compliance measures
 - Release limits (cumulative curies)
 - Individual dose limits (annual)
 - Ground water concentration limits

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Case Study: 40 CFR 191 Disposal Standards

- Regulatory time frame is 10,000 years
- All release and exposure pathways are considered
- Scenarios
 - "Significant" events included; "unlikely" events excluded
 - Human intrusion assessed for release limits only
- Receptor
 - Surrounding geologic media part of containment system ("controlled area")
 - Compliance measured at limits of institutional control
 - Special protections for ground water

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Case Study: 40 CFR 191 Disposal Standards

- Treatment of uncertainty
 - Probabilistic performance assessment
 - "Reasonable expectation" of compliance: "Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word."
- Compliance limits
 - Two compliance points for release limits
 - Limits proportional to inventory of nuclides
 - Small chance (0.1) of exceeding limits (normalized)
 - Very small chance of greatly exceeding limits (0.001, 10 times normalized limits)
 - Includes consideration of human intrusion
 - Individual protection: 15 mrem/yr (undisturbed)
 - Ground water protection: equivalent to present-day drinking water limits (undisturbed)

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Case Study: - 40 CFR 191 Disposal Standards

- Assurance Requirements
 - Active institutional controls (no credit after 100 years)
 - Monitoring (without disruption of disposal system)
 - Passive institutional controls and markers
 - Engineered barriers
 - Avoidance of resource-rich areas
 - Retrieval of wastes not precluded
- Significant details are left to licensing agency
 - Definition of "unlikely" and "significant" events
 - Selection of statistical measures and confidence
 - Key assumptions on scenarios, receptor characteristics, social and demographic changes
 - Quality assurance, peer review, parameter estimation

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Key Lessons

- Must pay attention to process and end result
 - Public confidence depends on both
 - Legal challenges (in U.S.) can be based on either aspect
- National and international views evolve
 - Keep in mind that the framework as a whole must be protective and credible
 - Balance two competing demands
 - Make goals and compliance measures as straightforward and understandable as possible...
 - While leaving adequate flexibility to accommodate evolving priorities and unanticipated issues
- More detailed licensing criteria – based on the safety standards – are necessary for effective implementation
 - Allows greater flexibility in underlying standards (as discussed above)
 - Later decisions are not less important—but more detailed and site-specific
- Continuing dialogue and evaluation of regulations is essential
 - Open, public processes continue to be important or confidence can erode.